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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,264	01/14/2002	Lynette Fouser	22058-532	4514

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,264	FOUSER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16,18,71 and 73-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14-16, 18, 71, 76 and 77* is/are rejected.

7)☒ Claim(s) *13 and 73-75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/24/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 21 November 2005 is acknowledged and entered. Following the amendment, claims 12 and 71 are amended.

Currently, claims 12-16, 18, 71, 73-77 are pending and under consideration.

Withdrawal of Objections and Rejections:

The prior art rejection of claims 12-16, 18, 71 and 73-77 under 35 U.S.C. 102(e) as being anticipated by Goddard et al., US6,740,520 B2, is withdrawn in view of applicant's argument.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 and the dependent claims 14-16, 18, 71, 76 and 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a polypeptide of SEQ ID NO:4, and functional variants with at least 95% identity thereto, does not reasonably provide enablement for claims to a variant at least 90% identical to SEQ ID NO:4, and comprising amino acids 67-98 of SEQ ID NO:4 and SEQ ID NO:13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim 12 is directed to functional variants that are at least 90% identical to SEQ ID NO:4 and comprises amino acids 67-98 of SEQ ID NO:4. Enablement is not commensurate in scope with the claim to those variant polypeptides. The specification discloses the amino acid

sequence of SEQ ID NO:4 and several specific amino acid substitutions in SEQ ID NO:4 (as indicated in SEQ ID NO:13-19), no other variants of SEQ ID NO:4 meeting the limitations of these claims were ever identified or particularly described. Additionally, the specification provides no further information about the structural and functional relationship within the sequence of SEQ ID NO:4 as to which regions would be tolerant of modification and which would not regarding to retaining the functional activities of the polypeptides. Although the presence of amino acids 67-98 of SEQ ID NO:4 is required, it has not been indicated that this region is responsible for the activity of the polypeptide. In order to make a sequence variant, for instance, with the reasonable assurance that it would have the desirable property of the invention, such as binding IL-10 or IL-22, the artisan would need to know which regions of the disclosed molecule are responsible for the interaction underlying its biological function(s). The specification provides neither clear direction or enough guidance, nor working example to teach how to make a commensurate number of the claimed species. Therefore, in the absence of guidance, or working example, it is not reasonable to predict that a variant with 90% sequence identity to SEQ ID NO:4 and having amino acids 67-98 of SEQ ID NO:4 and SEQ ID NO:13 would retain the functional activity. As such, it would require undue experimentation to practice the invention in a manner commensurate in scope with the claims.

Due to the large quantity of experimentation necessary to generate the infinite number of variants recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the lack of predictability of the structure of a functional variant, the complex nature of the invention, and the breadth of the claims which embraces a broad class of structurally diverse variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 12, 14-16, 18, 71, 76 and 77 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polypeptide at least 90% sequence identical to SEQ ID NO:4, comprising amino acids 67-98 of SEQ ID NO:4, and binding IL-10 or IL-22. The specification merely discloses *one* amino acid sequence of the soluble CRF2-like polypeptide having SEQ ID NO:4, and the specific amino acid substitutions in SEQ ID NO:4 as indicated in SEQ ID NO:13-19. No other variant of SEQ ID NO:4 meeting the limitation of the claims was ever identified or particularly described.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claim are a partial structure in the form of a recitation of percent identity, and the functional activity of binding IL-10 or IL-22. The specification does not teach the structural and functional relationship of the polypeptide, and it is not clear whether the required fragments of SEQ ID NO:13 and amino acids 67-98 are associated with the functional activity of the molecule. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the polypeptide of SEQ ID NO:4, and those with specific substitutions as indicated in SEQ ID NO:13-19, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides (generalized 90% variants). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In the instant application, applicants have a single polypeptide with a specific function that has not been correlated to any particular structural regions. Therefore, only isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:4, and those with specific amino acid substitutions as indicated in SEQ ID NO:13-19, but not the full breadth of the claims (generalized 90% variants) meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion:

No claim is allowed.

Claims 13 and 73-75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/15/06